

CLAIMS:

We claim:

1. A method, comprising:
 - selecting a diverse group of sera, the diverse group of sera having different characteristics;
 - applying each of the diverse group of sera to at least one spot on a plurality of different biochips;
 - performing mass spectrometry on each of said plurality of biochips;
 - generating a biochip model based at least in part on the spectra obtained from the plurality of different sera and biochips;
 - applying a test serum to a spot on a biochip;
 - performing mass spectrometry on the test serum to obtain a spectrum associated with the test serum;
 - mapping the spectrum obtained from said performing to the biochip model; and
 - determining whether the spectrum maps to the biochip model.
2. The method of claim 1, said generating further comprising:
 - selecting a cluster that contains the greatest number of vectors from the spectrum to define the biochip model.
3. The method of claim 1, said determining further comprising classifying a biological state from the spectrum based on a predetermined model.
4. The method of claim 1, wherein if said determining determines that the spectrum does not map to the biochip model, and the biochip being a first biochip, the method further comprising:
 - repeating the steps of applying, performing, mapping, and determining for a second biochip.
5. The method of claim 1, said selecting further comprising:
 - selecting at least two different sera from a pool of diverse sera, the pool of diverse sera consisting of: serum from healthy males, serum from healthy females, serum from males

afflicted with a disease, serum from females afflicted with a disease, serum from persons of different races, serum from persons of different ages.

6. The method of claim 1, wherein the generating includes:
identifying at least one cluster common to the each serum of the diverse group of sera and at least one biochip; and
selecting only one cluster as part of the biochip model.
7. The method of claim 1, wherein the performing mass spectrometry on each of said plurality of biochips includes performing mass spectrometry on at least two types of biochips, the types of biochips being at least two of a cationic exchange biochip, an anionic exchange biochip, and an immobilized metal biochip.
8. A method of quality assurance employing a biochip model generated based on mass spectra obtained from application of a diverse group of sera to each of a plurality of different biochips, comprising:
applying a serum to a spot on a biochip;
performing mass spectrometry on the serum to obtain a spectrum associated with the serum and the biochip;
mapping the spectrum to a biochip model; and
if the spectrum maps to the biochip model, submitting the spectrum to a biological diagnostic.
9. The method of claim 8, said performing mass spectrometry further comprising:
performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.
10. The method of claim 8, wherein said biological diagnostic is a disease model capable of determining if the sample exhibits a disease state associated with the disease model.
11. The method of claim 8, the serum being a first serum and the biochip being a first biochip, the method further comprising:

applying a second serum a spot on a second biochip;
performing mass spectrometry on the second serum to obtain a spectrum associated with said second serum;
mapping the spectrum to a biochip model, the biochip model being associated with the second biochip; and
updating the mapping using data obtained from the spectrum from the second serum.

12. The method of claim 8, wherein the model includes only one cluster from among several clusters common to each of the diverse sera and the biochips and wherein the submitting a spectrum that maps to the biochip model includes submitting a spectrum that maps to the selected cluster.

13. A method, comprising:

applying each of a diverse group of sera to at least one spot on a plurality of different biochips;
performing mass spectrometry on each of said plurality of biochips and on each serum of the diverse group of sera;
generating a biochip model based at least in part on the spectra obtained from all of the plurality of different biochips;
performing mass spectrometry on a test serum applied to a spot on a test biochip to obtain a spectrum associated with the test serum and the test biochip;
mapping the spectrum to the biochip model; and
determining whether the test serum and biochip produce a spectrum within a predetermined tolerance.

14. The method of claim 13, said performing mass spectrometry further comprising:
performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

15. The method of claim 13, further comprising:
if the spectrum maps to the biochip model, submitting the spectrum to a disease model to determine if the sample exhibits a disease state associated with the model.

16. The method of claim 13, the serum being a first serum and the biochip being a first biochip, the method further comprising:

- applying a second serum to a spot on a second biochip;
- performing mass spectrometry on the second serum to obtain a spectrum associated with the second serum;
- mapping the spectrum to a second biochip model, the second biochip model being associated with the second biochip bearing the applied second serum;
- updating the mapping using data obtained from the spectra from the second serum.

17. The method of claim 13, wherein determining whether a serum and biochip are producing spectra within a predetermined tolerance includes:

- identifying one of a first hypervolume and a first volume such that one of the first volume and the first hypervolume excludes a significant portion of one of a second volume and a second hypervolume, the one of a second volume and a second hypervolume being the total volume or hypervolume of an n-dimensional space.

18. A method of quality assurance employing first and second biochip models, each generated based on mass spectra obtained from application of a diverse group of sera to each of a first and second different biochip types and having a cluster associated with each of the first and second biochip types, comprising:

- applying a serum to a spot on a first biochip associated with a biochip model;
- performing a first mass spectrometry on the serum disposed on the first biochip to obtain a spectrum associated with the serum;
- mapping the spectrum obtained from said performing a first mass spectrometry to the biochip model;
- determining that the spectrum does not map to a cluster associated with the first biochip;
- applying the serum to a spot on a second biochip the second biochip being associated with a second cluster;
- performing a second mass spectrometry on the serum applied to the second biochip to obtain a second spectrum associated with the serum; and
- mapping the spectrum obtained from said performing a second mass spectrometry to the biochip model.

19. The method of claim 18, wherein the first and second biochip are associated with the same cluster.
20. The method of claim 18, wherein the first and second biochip are associated with different clusters.
21. The method of claim 18, said first performing a mass spectrometry further comprising:
performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.
22. The method of claim 18, further comprising:
submitting a spectrum that maps to one of the first and second biochip models to a disease model to determine if the sample exhibits a disease state associated with the disease model.
23. A method, comprising:
selecting a diverse group of sera, the diverse group of sera having different characteristics;
separating proteins within at least one sera of the diverse group of sera using a bioassay process;
performing mass spectrometry on at least one serum of the diverse group of sera;
generating a control model based at least in part on the spectra obtained from the at least one serum of the diverse group of sera;
separating proteins within a test serum using a bioassay process;
obtaining data from the at least one serum of the diverse group of sera, the data including a spectrum associated with the test serum and the bioassay process;
mapping the spectrum obtained from said performing to the control model; and
determining whether the spectrum maps to the model.
24. The method of claim 23, said generating further comprising:
selecting a cluster that contains the greatest number of vectors from the spectrum to define the control model.
25. The method of claim 23, said determining further comprising:

classifying a biological state from the spectrum based on a predetermined model.

26. The method of claim 23, wherein if said determining determines that the spectrum does not map to the control model, the method further comprising:

repeating the steps of separating, performing, mapping, and determining for a second biochip.

27. The method of claim 23, wherein the generating includes:

identifying at least one cluster common to the each serum of the diverse group of sera and the bioassay process; and

selecting only one cluster as part of the control model.